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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/593,362

09/18/2006

Stefan Verseck

009848-0356699

1298

27500

7590

02/22/2010

PILLSBURY WINTHROP SHAW PITTMAN LLP

ATTENTION: DOCKETING DEPARTMENT

P.O BOX 10500

McLean, VA 22102

EXAMINER

JOIKE, MICHELE K

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

02/22/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/593,362	<b>Applicant(s)</b> VERSECK ET AL.	
	<b>Examiner</b> Michele K. Joiike	<b>Art Unit</b> 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/8/10</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Receipt is acknowledged of a reply to the previous Office Action, filed December 8, 2009. Claims 1-11 are pending, claims 9 and 11 have been withdrawn by Applicant, and claims 1-8 and 10 are examined. Any rejection of record in the previous Office Action, mailed September 1, 2009 that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

Art Unit: 1636

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6-8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nojiri et al.

Nojiri et al (IDS reference, especially pp. 696-697, 700, 702, Figure 1 and Table 1) teach expressing two plasmids simultaneously in E. coli. The plasmids are pET plasmids. The first plasmid, pRCN104 contains both the alpha and beta subunits of nitrile hydratase derived from rhodococcus. The second plasmid, pHSG $\beta$ , contains the beta subunit of nitrile hydratase, but not the alpha subunit. Both plasmids contain the T7 promoter and contain other sequences.

It would have been obvious to one of ordinary skill in the art to not have the alpha and beta subunits on the same plasmid because Nojiri et al teach two separate plasmids, one with alpha and beta subunits and one with just the beta subunit. Having just the beta subunit on a plasmid allows for expression of the subunit, in other words, there appears to be no difficulty in separating the two subunits. One of skill in the art knows that only one alpha subunit and one beta is needed for nitrile hydratase to function, therefore it would be obvious to remove the beta subunit from the first plasmid. In fact, when both alpha and beta subunits were present together, the expression of the beta subunit was fairly low as compared to the alpha subunit. However, when beta was expressed separately on a plasmid, there was increased NHase activity. Subunits alpha and beta present in a plasmid was known. All of the claimed elements were known in the prior art and one skilled in the art could have separated the subunits by

Art Unit: 1636

known methods with no change in their respective functions, and the separate plasmids, with each plasmid containing either the alpha or beta subunit, would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nojiri et al as applied to claims 1-4, 6-8 and 10 above, and further in view of Nishiyama et al.

Nojiri et al teach all of the limitations as described above. In addition, contained on plasmids pRCN104 and pHSG $\beta$  is orf1188, which encodes a polypeptide that is homologous to p47K. However, they do not teach p47K in the plasmids.

Nishiyama et al (J. Bac. 173(8): 2465-2472, 1991, especially p. 2465) teach a plasmid containing the orf encoding p47K transformed into E. coli.

The ordinary skilled artisan, desiring have a plasmid containing p47K, would have been motivated to combine the teachings of Nojiri et al teaching plasmids containing orf1188, which encodes a polypeptide that is homologous to p47K, with the teachings of Nishiyama et al teaching a plasmid containing the orf encoding p47K transformed into E. coli, because Nishiyama et al state that p47K is important for expression of nitrile hydratase in E. coli. It would have been obvious to one of ordinary skill in the art because Nojiri et al teach that orf1188 is homologous to p47K, and both are important for functional expression of nitrile hydratase. Given the teachings of the prior art and the level of the ordinary skilled artisan at the time of the applicant's invention, it must be considered, absent evidence to the contrary, that said skilled

Art Unit: 1636

artisan would have had a reasonable expectation of success in practicing the claimed invention.

***Response to Arguments Concerning Claim Rejections – 35 USC § 103 (a)***

Applicant's arguments filed December 8, 2009 have been fully considered but they are not persuasive.

The following grounds of traversal are presented:

Applicants argue that there would be no motivation to modify the expression system of Nojiri et al since they produced a large amount of functional NHase.

Nishiyama et al fail to remedy the deficiencies of Nojiri et al.

Applicants' arguments have not been found persuasive for the following reasons.

As discussed above, Applicants are claiming a plasmid with an alpha subunit only, and a plasmid with a beta subunit only. Nojiri et al teach a plasmid with the alpha and beta subunits, and a plasmid with the beta subunit. The only difference is the presence of an extra beta subunit on the first plasmid. Nojiri et al teach that there were lower amounts of the beta subunit produced when alpha and beta were on the same plasmid, and that incorrect folding of NHase was partly due to the shortage of the beta subunit. Expressing the beta subunit on a separate plasmid increased NHase activity. Therefore one of skill in the art would have been motivated to separate the alpha and beta subunits in order to get better NHase activity and increased production of the beta subunit. There are no deficiencies for Nishiyama et al to cure, as just discussed.

***Allowable Subject Matter***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike whose telephone number is (571)272-5915. The examiner can normally be reached on M-F, 10:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1636

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michele K. Joike/  
Primary Examiner, Art Unit 1636

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